K06 1720

Section 3 - 510(k) Summary JAN 3 1 2007
Re: 061720

This 510(k) summary of safety and effectiveness for the Cosmelight Intense Pulsed Light system by Penntack Enterprises Inc. is submitted in accordance with the requirements of the Safe Medical Devise Act (SMDA) of 1990 and follows the office of Devise Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant :	Penntack Enterprises Inc.
Address :	3321 NW 79 ST. Miami, FL 33147
Contact Person :	Paul Pena (Director)
Telephone :	305-835-0411
Preparation Date :	May 5, 2006
Device Trade Name:	Cosmelight
Common Name :	Intense Pulsed Light System
Classification Name	Laser surgical instrument for use in general and plastic and dermatology. 21 CFR 878.4810 Product Code: GEX Panel: 79
Legally-marketed Predicate Devices:	The Cosmelight is substantially equivalent to the following currently marketed devices: Lumenis Inc IPL Quantum, K020839 Palomar Inc. EsteLux, K020453 McCue Plc. McCue Energist ULTRA, K040659 ***DDD A/S , Ellipse I^2PL, K060516***
System Description:	The Cosmelight Intense Pulsed Light System is comprised of the following main components: • A control console unit. • A control and color display panel. • Two removable handpieces with an integrated trigger switch and a Cooling System (a cooling device integrated into the handpieces. Quick Cool Handle (QCH) • Power supply.
Indicated Use :	***The Cosmelight Intense Pulsed Light System (and its accessories) are indicated for use in surgical, aesthetic and cosmetic applications (requiring photothermolysis, photocoagulation and dermatology) in the treatment of acne, various benign pigmented lesions and hair removal as follow:*** ***1. Intense Pulse Light Energy Wavelengths from 400 - 950 nm are indicated for the treatment of acne.*** ***2. Intense Pulse Light Energy Wavelengths from 560 - 120 0nm are indicated for the treatment of benign pigmented (epidermal***

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	and coetaneous) lesions including warts, scars and striae. For the treatment of benign (cutaneous) vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiormas, poikiloderma of civatte, leg veins, facial veins and venous malformations. ***3. Intense Pulse Light Energy Wavelengths from 700 - 1200 nm are indicated for the treatment of unwanted hair (i.e., hair removal).*** 4. Quick Cool Handle (QCH) The Quick Cool Handle is indicated for use in cooling the epidermis at the treatment Site prior to, during and after light or laser treatment in general surgery, plastic surgery And dermatology to : • Reduce pain associated with light or laser treatments (via partial anesthesia from Cooling). • Minimize thermal injury, including thermal necrosis, to non target skin and skin Structures during light or laser treatments, thus reducing the possibilities of scabbing, scarring, hypo and / or hyper pigmentation. • Allows the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatme of vascular or pigmented lesions.
Performance Data :	The differences in specifications of the Cosmelight system and the Predicate devices do not result in different performance or raise new questions of safety and efficacy.
Conclusion :	Based on the foregoing, the Cosmelight system is substantially Equivalent to the legally-marketed predicate devices mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Penntack Enterprises, Inc.
% Mr. Paul Pena
Director
3321 NW 79th Street
Miami, Florida 33147

JAN 3 1 2007

Re: K061720
Trade/Device Name: Cosmelight
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 24, 2006
Received: November 28, 2006

Dear Mr. Pena:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): _____K061720_____

Device Name: Cosmelight

Indications for Use:

The Cosmelight Intense Pulsed Light System (and its accessories) are indicated for use in surgical, aesthetic and cosmetic applications (requiring photothermolysis, photocoagulation and dermatology) in the treatment of acne, various benign pigmented lesions and hair removal as follow:

1. Intense Pulse Light Energy Wavelengths from 400 - 950 nm are indicated for the treatment of: inflammatory acne.

2. Intense Pulse Light Energy Wavelengths from 560 - 1200 nm are indicated for the treatment of: benign pigmented (epidermal and coetaneous) lesions including warts, scars and striae. For the treatment of benign (cutaneous) vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiormas, poikiloderma of civatte, leg veins, facial veins and venous malformations.

3. Intense Pulse Light Energy Wavelengths from 700 - 1200 nm are indicated for the treatment of: unwanted hair (i.e., hair removal).

Prescription Use ___X____ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061720